

MEMORANDUM

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

THROUGH: Jenny Slaughter _____/S/ 7/21/06
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Kathleen L. Walker _____/S/ 7/18/06
Chief, Integrity, Committee and Conference Management Branch
Division of Ethics and Management Operations, OMO
Center for Devices and Radiological Health

SUBJECT: Conflict of Interest Waiver for Michael J. Olding, M.D.

I am writing to request a waiver for Michael J. Olding, M.D., a member of the General and Plastic Surgery Devices Panel of FDA's Medical Devices Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a). Waivers under section 208(b)(3) may be granted by the appointing official where "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved" and where the individual has made a disclosure of the financial interests at issue. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant Dr. Olding a waiver under section 208(b)(3).

Section 208(a) prohibits Federal executive branch employees, including special Government employees, from participating personally and substantially in matters in which the employee or his employer has a financial interest. Since Dr. Olding is a special Government employee, this individual is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to him or his employer.

Dr. Olding has been asked to participate in Panel deliberations on two premarket approval applications (PMAs), sponsored by [-----], for *Radiesse* indicated for 1) the correction of facial lipoatrophy (facial fat loss); and 2) the subdermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds.

Dr. Olding has advised the FDA that he has a financial interest that could potentially be affected by his participation in these matters. He reported owning [---] shares in [-----], currently valued at [-----], which represents [-] of his net worth. [-----] is a direct competitor to the PMA sponsor.

The functions of the Committee, as stated in its Charter, are to review and evaluate available data concerning the safety and effectiveness of marketed and investigational devices and advise the Commissioner of Food and Drugs regarding recommended classification of these devices into one of three regulatory categories; recommend the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advise on any possible risks to health associated with the use of devices; advise on formulation of product development protocols and review premarket approval applications for those devices classified in this category; review classification as appropriate; recommend exemption to certain devices from the application of portions of the Act; advise on the necessity to ban a device; and respond to requests from the Agency to review and make recommendations on the specific issues or problems concerning the safety and effectiveness of devices. As a member of the General and Plastic Surgery Devices Panel, Dr. Olding potentially could become involved in matters that affect Medicis Corp. Under section 208, Dr. Olding is arguably prohibited from participating in such matters. However, as noted above, you have the authority under 18 U.S.C. § 208(b)(3) to grant a waiver permitting this individual to participate in such matters as you deem appropriate.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Olding that would allow this SGE to participate in the matters identified below:

First, the [-----] stockholding represents a low percentage of the SGE's net worth and its total value is not so significant as to affect the integrity of the services the Government may expect from him.

Second, [-----] is one of 17 firms marketing or pursuing development of a device to correct facial lipoatrophy and facial wrinkles and folds. The availability of multiple firms/products should mitigate the potential perception of bias on the part of this SGE.

Lastly, the Federal Advisory Committee Act requires that committee memberships be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee. Also, the committee's intended purpose would be significantly impaired if the Agency could not call upon experts who have become eminent in their fields, notwithstanding the financial interest and affiliations they may have acquired as a result of their demonstrated abilities. Dr. Olding is Chief, Division of Plastic Surgery, and Associate Professor of Surgery, Division of Plastic and Reconstructive Surgery, at George Washington University. Because of his extensive experience in plastic and reconstructive surgery as well as cosmetic plastic surgery including the use of injectable wrinkle relaxing and filling products, we believe that Dr. Olding's participation in the deliberations will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

DECISION:

Waiver denied.

/S/ 7/24/06

 Randall Lutter, Ph.D. Date
 Associate Commissioner for Policy and Planning